

II. REMARKS

A. Status of the Claims

Claims 1-8 were originally filed with the case on June 2, 2005. A Restriction Requirement mailed on April 15, 2008, stated that the originally filed claims were directed to two patentably distinct inventions. In a Response to Restriction Requirement filed on September 15, 2008, Applicants elected the invention of Group I, that is, claims 1-4, directed to a method of treating glaucoma. All claims were rejected in an Office Action mailed on November 26, 2008. In a Response to Office Action filed on February 26, 2009, claims 1 and 4 were amended, claim 2 was cancelled and claims 5-8 were withdrawn from consideration. The outstanding Final Official Action, mailed on June 10, 2009, states that claims 3 and 4 are also withdrawn from consideration as not encompassing the elected species. Claim 1 was amended in a Response to Final Office Action filed on August 14, 2009. A Request for Continuing Examination was filed on September 2, 2009, after receipt of an Advisory Action maintaining the rejections with respect to claim 1. The present Office Action maintains the rejection of claim 1. Claim 1 is amended, and no claims are cancelled or added herein. Claim 1 remains pending.

B. The Claims are Not Anticipated by Banerjee

Finally, the Action rejects claims 1-2 under Section 102(a) and 102(e) as being anticipated by Banerjee (U.S. Patent Pub. 2002/0160979). Banerjee is said to teach a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions disclosed in Banerjee are said to include neovascular glaucoma. Applicants respectfully traverse.

The present invention is directed to a method for lowering intraocular pressure by topically administering to the eye of a patient a composition containing a cathepsin K antagonist. Banerjee does not describe methods for lowering intraocular pressure or topical ocular administration to the eye of a patient suffering from elevated intraocular pressure.

The objective of Banerjee is to inhibit angiogenesis, which it defines as “the growth of capillary endothelial cells which form new blood microvessels” (See ¶ [0064]). The main focus of the methods described in Banerjee is the treatment of tumors, which are known to result from angiogenesis. Furthermore, Bannerjee states that administration of the compound is typically systemic (See ¶ [0179]). The Action argues that the routes of administration described in Banerjee include topical, citing paragraph 192. A close review of paragraph 192 reveals that the entire paragraph discusses the treatment of tumors. For example, paragraph 192 states that “although it is expected that the administration may be by intraperitoneal injection near the disease tissue, e.g., tumor mass, to minimize side effects, the preferred manner of injection is expected to be intravenous.” The following sentence lists a number of other options for delivery of the active agent to the disease tissue (i.e., tumor), including topical application to the tumor. The final sentence of the paragraph states “regarding intraperitoneal injection near the disease tissue, e.g., tumor mass, it is expected that micro-pumps may be implanted in or near the disease tissue, e.g., tumor mass, to administer the dose in a manner similar to insulin pumps.” Applicants submit that the skilled artisan would not read this one occurrence of the term “topical” in the application, which is included in the context of treating tumors, as referring to topical ocular administration.

Applicants reiterate the Federal Circuit's position that "absence of a claim element from a prior art reference negates anticipation." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Since Bannerjee lacks a teaching of lowering intraocular pressure and of topical ocular administration, it cannot be said to anticipate the claimed invention.

In light of the foregoing arguments, Applicants respectfully request that the anticipation rejection based on Bannerjee be withdrawn.

C. Claim 1 is Patentable Over Banerjee

Finally, the Action rejects claim 1 as being obvious over Banerjee (2002/0160979). The Action acknowledges that Banerjee fails to teach a method of lowering intraocular pressure with the administration of a cathepsin K antagonist. Nevertheless, the Action takes the position that it would have been obvious to utilize the method for inhibiting angiogenesis as taught by Banerjee comprising administering a composition comprising a nucleoside, particularly tunicamycin, for conditions such as neovascular glaucoma for lowering intraocular pressure resulting from angiogenesis factors. Applicants respectfully traverse.

The present invention is directed to a method for lowering intraocular pressure in a patient suffering from glaucoma by topically administering to the eye of a patient a composition containing a cathepsin K antagonist. The Action relies on Hunter (U.S. Patent 5,886,026; U.S. Patent Application 2002/0192280) and Gurwood (Review of Optometry November 1999 Case Report) to support its position that intraocular pressure is characteristic for neovascular glaucoma and asserts that the inhibition of the angiogenesis would inherently inhibit the cascade in neovascular glaucoma affecting the intraocular pressure which has been known and pursued in the art for many years. The Action dismisses Applicants previous

arguments relative to Hunter and Gurwood stating that “[Hunter and Gurwood] are utilized to show that intraocular pressure is characteristic for neovascular glaucoma.” (Action, page 11). Regardless of the Action’s purpose in relying on Hunter and Gurwood, the full spectrum of the disclosures contained therein must be analyzed as to how the skilled artisan would interpret their teaching.

As explained in more detail in the Response to Final Office Action filed on August 14, 2009, Hunter teaches that conservative therapies for the neovascularization may be effective at treating neovascular glaucoma while the anterior chamber angle is still open (i.e., before intraocular pressure is elevated) (Col. 34, lines 3-10), but that “once the angle closes surgical intervention is required in order to alleviate the [intraocular] pressure.” It is submitted that, after reading Hunter, the skilled artisan would be even more convinced that neovascular glaucoma must be treated by using anti-angiogenic factors before intraocular pressure becomes elevated as a result of the progression of the disease. Once intraocular pressure becomes elevated, the skilled artisan would be led to believe that one must perform surgery on the eye in order to decrease the intraocular pressure. In other words, the skilled artisan would not expect that anti-angiogenic factors would be effective in relieving elevated intraocular pressure resulting from neovascular glaucoma because the disease will have progressed too far by that point. The Hunter ‘290 application contains the same discussion of neovascular glaucoma that Hunter ‘026 contains. Therefore, Hunter must be fairly read as teaching away from the claimed invention, especially in combination with Banerjee.

In light of the foregoing arguments, Applicants respectfully request that the obviousness rejection based on Bannerjee be withdrawn.

D. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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Date: February 4, 2010